UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,990	01/03/2002	Vijay Sharma	RELIA P-106	7830

30294 7590 10/03/2002

LACKENBACH SIEGEL
ONE CHASE ROAD
SCARSDALE, NY 10583

EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,990	SHARMA ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-37 as originally filed are pending and under examination. Claims 1-14 are drawn to a kit for amplifying HCV nucleic acid comprising two HBV amplification primers. Claims 15-25 are drawn to a kit for detecting HCV nucleic acid comprising an HCV oligonucleotide probe. Claims 26-37 are drawn to a method for detecting HCV nucleic acid comprising amplification using two HCV primers and detection using an oligonucleotide probe.

Claims 2 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 does not further limit the subject matter of claim 1 from which it depends because claim 2 requires a first amplification primer that comprises "at least twenty four continuous bases" but the first amplification primer recited in claim 1 as SEQ ID NO 1 has twenty four bases. Similarly, claim 4 does not further limit the subject matter of claim 1 because claim 4 requires a second amplification primer that comprises "at least twenty four continuous bases" but the second amplification primer recited in claim 1 as SEQ ID NO 2 has twenty four bases.

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 does not further

limit the subject matter of claim 15 from which it depends because claim 16 does not recite any structural or physical modification to the kit composition of claim 15.

Claims, 7, 22, and 34 are objected to because of the following informalities:

Claim 7 is objected to because "myeloblastosis" is misspelled in line 2.

Claims 22 and 34 are objected to because "horseradish" is misspelled in line 2 of claim 22 and in line 2 of claim 34.

Claim 34 is also objected to because "fluorescein" is misspelled twice in line 2.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15 and 26 are indefinite in reciting "primer having the sequence ..." and/or "probe having the sequence" since it is not clear whether "having" is intended to be open language, equivalent to "comprising," or closed language, equivalent to "consisting of." Consistent with the practice of giving claim language its broadest reasonable interpretation, "having" has been interpreted as open language.

Claims 3, 5, 12, 20, and 32 are indefinite in reciting, in the case of claims 3, 5, and 20, "... an amount of ... pM" and, in the case of claims 12 and 32, "an amount of ... μM" since pM and μM are units of concentration and not "amount." A definite recitation

of the amount of a substance present in a solution would require reciting both volume and concentration.

Claim 17 is indefinite in reciting "... the oligonucleotide probe has a label at their 5' end" without clear antecedent since claim 17 depends from claim 153, which recites a single oligonucleotide probe. It is suggested that the language of claim 15 would be improved in clarity if it were amended to read, e.g., "... the oligonucleotide probe has a label at its 5' end."

Claims 25 and 36 are indefinite in reciting "substrate is present in an amount of ... μL" since μL is a unit of volume and does not represent the actual amount of substrate present.

Claim 26 is unclear and apparently contains an error in line 3; there appears to be an omitted word between "nucleic acid" and "a biological sample."

Claim 26 is also indefinite because does not recite "reverse transcription" as an active process step, such as "reverse transcribing" or "adding an RNA dependent RNA polymerase under conditions allowing reverse transcription," for example.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,580,718 to Resnick et al., cited on PTO 892, attached.

Resnick et al. disclose primers and kits for detection of hepatitis C. In particular, Resnick discloses a primer having SEQ ID NO:5, which is identical to SEQ ID NO:1 as instantly claimed, and a primer having SEQ ID NO:18, which is identical to SEQ ID NO:2 as instantly claimed, as well as kits and methods using RNA dependent RNA polymerase, such as avian myeloblastosis polymerase, for reverse transcription and Taq polymerase for amplification (see, e.g., col. 15, line 35-col. 16, line 17).

Claims 15 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Geiger et al., WO 200137291, as evidenced by STIC GenEmbl sequence search result, Accession AX147016. Geiger et al. disclose a probe for detecting HCV that is identical to SEQ ID NO:3 (Example 7; SEQ ID NO:10).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

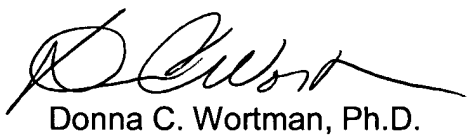
Claims 3, 5, 7, 9, and 11-14, are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,580,718 to Resnick et al. as applied to claims 1, 2, 4, 6, 8, and 10, above. Resnick teaches HCV primers and methods as discussed above, and discloses that the required assay conditions, reagents, amounts, and labels are conventional and well known, rendering obvious the subject matter of claims 3, 5, 7, 9 and 11-14 to one of skill in the art at the time the invention was made.

Claims 17-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,580,718 to Resnick et al. in view of Geiger et al., both cited above. Resnick teaches amplification of HCV nucleic acids using primers as discussed above and as well as detection of amplified nucleic acids using probes that hybridize to the amplified HCV nucleic acid. Resnick also teaches kits, reagents, and assay formats for performing such detection assays and teaches the use of probes, preferably labeled, that hybridize to amplified regions conserved across strains but does not teach the specific probe having SEQ ID NO:3. Geiger teaches an HCV-specific probe that has SEQ ID NO:3. It would have been obvious to one of ordinary skill in the art to have substituted the HCV-specific probe that has SEQ ID NO:3 of Geiger for the probes of Resnick for expected equivalent results because Resnick discloses that a probe that hybridizes to a conserved region that lies between the two primers is suitable and because Geiger discloses that the HCV probe having SEQ ID NO:10, corresponding identically to Applicant's SEQ ID NO:3 probe, is suitable for the specific detection of HCV nucleic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
September 30, 2002